4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2013-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Arsanilic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of a new animal drug application (NADA) for an arsanilic acid Type A medicated article at the sponsor's request because the product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, email: john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234 has requested that FDA withdraw approval of NADA 008-019 for PRO-GEN (arsanilic acid) Type A medicated article because the product, used to manufacture Type B and Type C medicated feeds, is no longer manufactured or marketed.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 008-019, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE

10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.62 [Amended]

2. In § 558.62, remove and reserve paragraphs (a)(1), (a)(2), (c)(1)(i), and (c)(1)(ii); and in paragraphs (c)(1)(iii), (c)(1)(iv), (c)(1)(v), (c)(1)(vi), and (c)(1)(vii), in the "Arsanilic acid in grams per ton" column, add "90".

Dated: November 20, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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